HYPODERMIC SYRINGE NEEDLE ASSEMBLY AND METHOD OF MAKING THE SAME

REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of 10/157,885, filed May 31, 2002, which is a continuation-in-part of 10/133,491, filed on April 29, 2002, which is a continuation-in-part of 09/613,753, filed July 11, 2000, which is a continuation-in-part of 09/471,094, filed December 23, 1999. The disclosure of the applications cited above is incorporated by reference herein. Additionally, the disclosure of each of the following applications having Owais Mohammed named as inventor is incorporated by reference herein: 09/218,040, filed December 22, 1998; and 09/316,047, filed May 21, 1999.

BACKGROUND OF THE INVENTION

The present invention generally refers to hypodermic syringe needles for medical use. More particularly, the invention relates to hypodermic safety needles which retract into a container when not in use, preventing unintentional contact with the needle.

Prior art injection needles feature hollow needles which extend through a plastic hub. To prevent a user from accidentally pricking himself with the point of a needle, the needle is covered with a removable cover. Such covers frictionally engage the plastic hub, and may be readily removed once the needle is attached to a syringe barrel. After use, the cover may be reattached to the needle assembly, which is then separated from the syringe barrel and discarded. However, there is an unacceptable risk of accidental injury resulting from contact with the point of the needle during the recapping step. This is particularly dangerous as biological fluids contaminating the needle could enter the user's bloodstream. An improved means of covering a used injection needle is needed.

A wide variety of needles having a means for shielding a syringe needle from accidental contact with a user's fingers have been developed. For example, U. S. 4,900,311, "Hypodermic Syringe", issued to Stern on Feb. 13, 1990, relates to a hypodermic syringe having a syringe barrel, an injection needle attached to the syringe barrel, and a needle guard of elliptical cross section disposed around the syringe barrel. The needle guard may be moved from a first position which covers the needle to a second position which exposes the needle. When the guard is in the second position, tabs on the interior of the guard engage slots on the syringe barrel, locking the guard into position. When the tabs are released from the slots by squeezing the elliptical guard along its longitudinal axis, a spring causes the guard to move into the first position, hiding the needle. The entire syringe assembly is then discarded.

This device, while useful, does have certain drawbacks. The syringe barrel used with this assembly has a highly specialized structure; a generic syringe barrel cannot

readily be substituted. Also, the syringe barrel cannot readily be sterilized and reused. No provision for separation of the needle from the syringe barrel without removing the syringe needle from the protective needle guard is provided. Finally, there is the risk of accidentally squeezing the elliptical needle guard, causing the spring to move the needle guard into a position which conceals the needle prior to use of the needle.

U. S. 4,664,654, "Automatic protracting and locking hypodermic needle guard", issued to Strauss on May 12, 1987, relates to a two-piece needle shield comprising a sliding member and a stationary member. A latch holds the sliding member in position. When the latch is released, a spring causes the sliding member to retract inside the stationary member, exposing the needle. However, this device causes the user to place his hand in proximity to the needle at the time it is exposed, increasing the likelihood of injury from accidental contact with the needle.

U. S. 5,246,428, "Needle Safety Mechanism", issued to Falknor on Sept. 21, 1993, relates to a needle safety mechanism comprising a base adapted to be fixed with respect to the needle, and a sheath which is movable between a first position which exposes the needle and a second position which covers the needle. A latch cooperative between the base and the sheath may be used to releasably latch the sheath in the position which covers the needle. A spring biases the sheath into the needle covering position. No mechanism for latching the sheath in a position which exposes the needle is provided, however. This may be an inconvenience for workers who wish to see the precise spot where they are administering an injection.

U. S. 5,279,579, "Self-recapping Injection Needle Assembly", issued to D'Amico on Jan. 18, 1994, relates to a self-capping injection needle assembly which includes a hub slidably positioned within a cylindrical cover adapted to receive a syringe barrel, and a needle mounted on the hub. A spring biases the hub into a position in which the needle is contained within the tubular cover. When the spring is compressed, the hub may slide into a position which exposes the needle. The hub includes a pin which slidably engages a longitudinal groove in the tubular cover. The groove includes a transverse leg adapted to receive the pin. When the pin is positioned in the transverse leg, the hub is releasably locked into a position which exposes the needle. The hub has a threaded female joint which may be screwed onto a syringe barrel having a corresponded threaded male joint. Different size tubular covers may be used for different size syringe barrels.

This device has certain disadvantages. First, in a medical environment time is often a critical factor. A more rapid method of affixing a needle to a syringe barrel than screwing it on is desirable. Also, only syringe barrels with a specific type of joint adapted to mate with the hub are usable with this device. Most commonly used medical syringe barrels have frusto-conical tips which frictionally engage syringe needle hubs having frusto-conical cavities therein; such commonly used barrels cannot be used with the threaded connections envisioned by D'Amico. D'Amico requires that a hub having a specific diameter must be used with a tubular cover having an inner diameter which is substantially equal to the hub diameter. Most commonly available syringe needle hubs have a single standard size, and cannot be used with a range of tubular cover sizes.

Therefore, D'Amico's invention necessitates creation of a range of expensive and specialized syringe needles having a range of hub sizes. Also, since the diameter of D'Amico's hub is very nearly equal to the interior diameter of the tubular cover, it is difficult to insert a hub having a protruding pin into the cover. An easy method of assembling such a device is desirable.

There is a long-felt need in the art for a safety needle assembly having a retractable needle which may be easily assembled, and which may be used with commonly available syringe barrels having frusto-conical tips which frictionally engage a syringe needle assembly. The required safety needle assembly must also avoid the other disadvantages of known prior art devices. It is an object of this invention to provide such a safety needle assembly.

SUMMARY OF THE INVENTION

The present invention provides a disposable hypodermic syringe needle which retracts into a container for safe disposal. The retractable needle assembly comprises:

a needle assembly, said needle assembly comprising a hub having an anterior end and a posterior end, a hollow needle passing through the hub and projecting from the posterior end of the hub; and a tubular sleeve connected with a peripheral edge of the hub and projecting from the anterior end of the hub, said sleeve having a radially directed hole therethrough; and

a tubular sheath having a wall with a radially directed hole therethrough, an anterior end, and a posterior end, said posterior end having an opening therethrough. The needle assembly is positioned within the tubular sheath with the hollow needle being directed toward the opening in the posterior end of the sheath. The needle assembly may be moved reversibly along the axis of the sheath between an exposed position in which the hollow needle passes through the opening in the posterior end of the sheath and a retracted position in which the hollow needle is contained within the tubular sheath. The retractable needle assembly further comprises a plurality of locking mechanisms, each designed to lock the needle assembly into a specified position. The needle assembly comprises a means for reversibly locking the needle assembly in its exposed position; a means for reversibly locking the needle assembly in its retracted position; and a means for permanently locking the needle assembly in its retracted position. In one embodiment, the permanent locking means comprises a radially-directed peg mounted on an exterior surface of the tubular sheath so that one end of the radially-directed peg is adapted to be pushed inwardly through the hole in the wall of the tubular sheath and through the hole in the tubular sleeve. This end of the radially-directed peg may not be withdrawn through the hole in the tubular sleeve after it has been pushed through the hole in the tubular sleeve. Other embodiments of the permanent locking means are also feasible.

Preferably, the tubular sheath or container features a tubular wall having a longitudinal slot therethrough. One end of the container is open so that a syringe barrel may be received therein. The second, or posterior, end of the container has an opening which is sufficiently large to allow a hypodermic needle to pass therethrough, but is too

small to allow the hub or a syringe barrel to pass therethrough. A spring may engage the hub of the needle assembly and a ridge on the interior of the wall of the second end of the container. This spring biases the hub away from the second end of the container so that the needle attached to the hub is hidden within the container. When the spring is compressed, the needle is able to pass through the opening of the posterior end of the container. A pin attached to the annular sleeve is slidably engaged by the longitudinal slot in the container wall, holding the needle within the container while allowing it to slide back and forth. A knob mounted on the pin is positioned outside the container. The knob is too large to pass through the longitudinal slot, and acts to position the hub of the needle along the axis of the container. When the knob is pushed toward the second end of the container, the hub moves toward the second end of the container, compressing the spring and causing the needle to emerge through the second open end of the container. A means for reversibly engaging the knob when the spring is compressed is also provided. This allows the needle to be retained in an exposed position.

The needle may be frictionally secured to a syringe barrel having a plunger slidably mounted therein. More specifically, a syringe barrel having a tip is secured to the needle assembly by inserting the tip of the syringe barrel into the cavity of the annular sleeve until the barrel tip is frictionally secured to the barrel sleeve. Additional features of the invention will be described in the detailed description of the preferred embodiments. Any syringe barrel having an appropriately shaped tip may be used with the inventive needle assembly.

Other embodiments of this invention are contemplated. The needle assembly of this invention may be attached to an IV tube and used for intravenous administration of fluids. Also, a modified needle assembly having a double-ended hypodermic needle that is affixed to a hub may be used to withdraw samples of venous blood.

DESCRIPTION OF THE DRAWINGS

Figs. 1a illustrates a side view of a preferred needle assembly for use in the syringe assembly of this invention.

Fig. 1b, 1c, and 1d illustrate cross-sectional views of preferred needle assembly.

Fig. 1d illustrates an end view of the needle assembly of Fig. 1a.

Figs. 2 and 3 show grooved containers designed to contain the needle of Fig. 1a.

Fig. 4 shows a retractable hypodermic safety needle within a container, with the needle in a retracted configuration.

Fig. 5 shows a retractable hypodermic safety needle within a container, with the needle in an exposed configuration.

Figs. 6a through 6g show various embodiments of locking mechanisms to hold a retractable needle in an exposed configuration.

Figs. 7, 8a, 8b, 8c, 9a, 9b, 9c, 9d, 9e, 9f, 10a, 10b, 10c and 10d show mechanisms to irreversibly lock a retractable needle in a retracted configuration.

Fig. 11 is an exploded view of the syringe of the current invention, showing how the pieces are assembled.

Fig. 12 illustrates the parts used to form an alternate version of the container of Fig. 2.

Fig. 13 is an exploded view of the retractable hypodermic safety needle within a container shown in Fig. 12.

Figs. 14 and 15 show a modified version of the apparatus of Fig. 4.

Figs. 16 and 17 show a second modified version of the apparatus of Fig. 4.

Fig. 18 shows a modified version of the needle assembly of Fig. 1a, for use in taking blood samples.

Fig. 19 shows an apparatus for taking blood samples, using the needle assembly of Fig. 18.

Fig. 20 shows how rigid ring 9a fits onto the tubular container of Fig. 2.

Fig. 21 shows the apparatus of Fig. 19 in use.

Fig. 22, 22a, 23a, 23b, 23c, 25c, and 25d show a needle assembly featuring an adjustable-length tube.

Figs. 24a, 24b, 25a, and 25b show different embodiments of the adjustable-length tube.

Fig. 26 shows the apparatus of Fig. 22 in use.

Fig. 27 shows a needle assembly for use with a catheter.

Fig. 28 shows a retractable needle for use with a catheter.

Fig. 29 shows a preferred housing design for use with a catheter.

Fig. 30 shows the needle assembly of Fig. 28 with a catheter attached thereto.

Figs. 31a through 31d show a catheter adapted for use with the catheter assembly of claim 27, said catheter having a stopcock assembly.

Figs. 32a, and 32b show means for reversible locking a needle assembly in the retracted and exposed positions.

Fig. 32c shows a means for reversibly locking a needle assembly in the exposed position using a tapered slot.

Fig. 32e shows a tapered sheath with a tapered slot.

Fig 33a shows a sectional view of permanent needle locking means in the open position.

Fig 33b shows a sectional view of the means of Fig. 32a in the locked position.

Fig. 33c shows a blind hole in the cross piece of Fig. 33a

Fig 33d shows a blind hemispherical hole in the cross piece of Fig. 33a.

Fig. 34a shows a sectional view of another one of the permanent locking mechanisms in the unlocked position.

Fig 33b shows the embodiment of Fig. 34a in the locked position.

Fig 33c is a plan view of the device of Fig 33a.

Fig. 34a shows another permanent locking mechanism of the invention in the unlocked position.

Fig.34b shows the embodiment of Fig. 34a in the locked position.

Fig. 34c is a plan view of the device of Fig. 34a.

Fig. 34d is an elevation view of the guard of Figs. 33 and 34.

Fig. 34e is an alternate embodiment of the device of Fig. 34a.

Fig. 35a is a partial sectional view of an alternate embodiment of the invention.

Fig 35b is a plan view of Fig. 35a showing the reversible tapered locking slot.

Fig. 35c is a rotated plan view of the device of Figs. 35a.

Fig 35d a sectional view of the tubular connector of Fig.35.

Fig.35e is a sectional of another tubular connector of Fig. 35.

Fig. 35 f is an alternate locking means for the device of Fig. 35a.

Fig 36a is a partial sectional view of another embodiment of the invention.

Fig. 36 b is a plan view of the device of Fig. 35a having a tapered slot.

Fig. 36 c is a partial plan view of Fig. 36a showing an alternate locking means..

Fig. 37 is a partial sectional view of an alternate embodiment of the invention.

FIG. 37 a is an alternate embodiment of the invention of Fig. 37.

Fig. 37 b is another embodiment of the invention of Fig.37a.

Fig. 38 is an alternate embodiment of the invention of Figs 33a-33d.

DETAILED DESCRIPTION

The needle used in the present invention is designed for use with a syringe comprising a plunger and a syringe barrel having a tubular wall with a defined outer diameter, where the barrel has an open end adapted to receive the plunger and a closed end having a cylindrically symmetric tip projecting therefrom. The tip of the barrel has a defined diameter which is less than the defined outer diameter of the syringe barrel and a longitudinal bore passing through the tip and the closed end of the barrel.

Fig. 1a illustrates a hypodermic needle for use in the syringe assembly of this invention. Needle 1 is affixed to hub 2. A hollow bore runs longitudinally through needle 1 and hub 2. An annular sleeve 3 is affixed to the outer periphery 4 of hub 2. A ledge 5

encircling hub 2 is defined by the edge of sleeve 3. Sleeve 3 defines a cavity 6 adapted to frictionally engage the tip of the syringe barrel, as shown in the cross-sectional views of Figs. 1b and 1c. The diameter of cavity 6 is sized to match the diameter of the tip of the syringe barrel, while being substantially smaller than the diameter of the outer diameter of the tubular wall of the syringe barrel, allowing the cavity 6 to fit over the syringe barrel tip without extending over the external surface of the wall of the syringe barrel. In one preferred embodiment, the interior surface of the sleeve defines a frusto-conical cavity 6, where the sleeve is adapted to frictionally engage a frusto-conical tip of a syringe barrel (Fig. 1b). In another preferred embodiment, the interior surface of the sleeve defines a cylindrical cavity of constant diameter, where the sleeve is adapted to frictionally engage a cylindrical syringe barrel tip of constant diameter (Fig. 1c). Alternatively, the interior surface of the tubular sleeve may be threaded, allowing it to engage a threaded male joint on the syringe barrel. If desired, the exterior surface of the tubular sleeve may be threaded, allowing it to engage a threaded female joint on the syringe barrel. Finally, the user may wish to connect the needle to a syringe barrel having a Luer-Loc® connector. Such a connector typically includes a threaded female joint on the syringe barrel, surrounding a non-threaded male joint on the syringe barrel. The interior surface of the tubular sleeve frictionally engages the inner male joint on the Luer-Loc® connector on the syringe barrel, while a flange 3a on the exterior surface of the tubular sleeve engages the threaded female joint on the syringe barrel, as shown in Fig. 1d.

A radially projecting member 7 is affixed to the outer surface of sleeve 3. A thumb rest knob or crosspiece 8 is mounted on member 7. Member 7 commonly takes the form

of a pin having a round cross section; however, other configurations are possible. Member 7 may have a square, rectangular, or oval cross section. If desired, 7 may have a length which is substantially greater than its width. The crosspiece may take any of several forms. It may be square. It may also be a round disk, a spherical knob, or a hemispherical knob. It may also take the form of a ring which encircles hub 2, without being connected to hub 2, except by means of stem 7. Crosspiece 8 should be positioned so that, when viewed along the axis of needle 1, piece 8 and pin 7 intersect at a right angle (Fig. 1e). Although pin 7 and crosspiece 8 may be manufactured separately and secured together, it is preferred that 7 and 8 be manufactured as a single piece.

Fig. 2 shows a grooved container designed to house the needle of Fig. 1a. The container has a tubular wall 9 having a longitudinal slot 10 therethrough. A first end of the container has an opening 13 adapted to receive a syringe barrel. The second end of the container has an opening 14 which is large enough to allow needle 1 to pass therethrough, but too small to admit a syringe barrel or a human finger. A ledge 15 on the second end of the container runs from the interior of wall 9 to the edge of opening 14. Slot 10 runs from a point near the first end of the container, without reaching the first end of the container, to a point near the second end of the container, without reaching the second end of the container. A second slot 10a, running a part of the way around the circumference of wall 9, intersects slot 10 near the second end of the container. A similar slot 10b intersects slot 10 near the first end of the container. Slots 10a and 10b are preferably parallel to each other. A series of circumferential ridges 120 may optionally be positioned on the exterior of the container, said ridges being effective to strengthen the

container, although this feature is not necessary for proper function of the invention. Slots 10a and 10b are preferably L-shaped slots, as shown in Fig. 2, or straight slots, as shown in Fig. 3. The slots 10a and 10b may have one or more teeth 200.

Although the container may be made in a single piece, it is preferred to manufacture the container in two pieces (Fig. 3). The first piece is a housing or a container having a tubular wall 9 with a longitudinal slot 10 therethrough, exactly as previously described; the sole difference is that the longitudinal slot 10 extends from the first open end of the container to a defined point near the second open end of the container, slot 10 being open-ended at the first open end of the container and closed at the second open end of the container discuss slots 10a & 10b. The second piece of the container is a rigid ring 9a having a first end and a second end, where the rigid ring 9a is positioned over the first open end of the container so as to close the open end of the longitudinal slot. Preferably, one end of the ring is flush with one edge of slot 10b without blocking slot 10b. To help hold the ring 9a in position on the wall 9 of the first piece of the container, the ring has a circumferential ridge on its interior surface, and the container has a circumferential groove on its exterior surface near the first open end of the container (Fig. 20). The rigid ring fits over the first open end of the container until the circumferential ridge snaps into the circumferential groove. Additionally, the rigid ring may have a longitudinal ridge on its interior surface, where the longitudinal ridge fits into the open end of the longitudinal slot so as to prevent the ring from rotating relative to the wall 9.

Fig. 4 shows how the needle assembly of Fig. 1a is contained within the container of Fig. 2. The needle assembly is positioned within the container with pin 7 slidably engaging slot 10. Crosspiece 8 helps to retain pin 7 within slot 10. Piece 8 is sufficiently large that it cannot pass through slot 10 into the interior of the container, and is rigidly secured to a defined position along the length of pin 7, where the defined position on pin 7 is chosen so that hub 2 of the needle assembly is positioned along the cylindrical axis of the container, as shown in the cross-sectional view of Fig. 4. More particularly, the distance between the axis of hypodermic needle 1 and crosspiece 8 is equal to the one half the external diameter of the wall 9 of the container. This retains needle 1 along the axis of the container. Removal of knob 8 would allow pin 7 to slip out of slot 10, causing hub 2 to fall against the inside of wall 9. Ring 9a prevents pin 7 from exiting the open end of slot 10. As shown in Fig. 4, 9a is flush with one edge of slot 10a. In general, the size of the container can be chosen so as to accommodate any size syringe. Thus, if a large syringe is to be used, a container having a large interior diameter is required. The maximum diameter of the combination of hub 2 and sleeve 3 can be selected so as to correspond to the interior diameter of the container wall 9. Thus, a specific needle-holding assembly having a specific hub size may be manufactured for each commonly used syringe size. Alternatively, a standard-sized hub and sleeve may be used in each case, regardless of the size of the syringe and/or container. This may be done by varying the length of pin 7, so as to match the distance between sleeve 3 and the wall 9 of the container.

A needle having a hub of any desired size may be used in a container having any desired radius without losing the desired axial orientation of needle 1 by simply changing the distance between the axis of needle 1 and crosspiece 8. This makes it unnecessary to manufacture a wide variety of needle hubs, with each needle hub being reserved for a different container size, as required by D'Amico.

A spring 16 is also positioned within the container, as shown in Fig. 4. A first end of spring 16 engages ledge 15 at the second end of container 1, while the second end of spring 16 engages ledge 5 encircling hub 2. The spring acts to bias hub 2 away from the second end of the container so that needle 1 is effectively concealed within the container. This allows the user to effectively handle the assembly without pricking his fingers. Preferably, the tip of the needle bore is positioned inside 14 (Fig. 4).

When one is ready to use the needle, needle 1 may be exposed by pushing hub 2 toward the second end of the container. This is most easily done by manually sliding crosspiece 8, attached to pin 7, along slot 10 with the user's thumb or finger. As hub 2 approaches the second end of the container, spring 16 is compressed and needle 1 passes through opening 14 in the container and is exposed. Since needle 1 is directed along the axis of the container, it is very easy to direct the needle through opening 14. When pin 7 reaches end 12 of slot 10, the needle is rotated by reversibly pushing pin 7 into slot 10a. Slot 10a acts as a stop, preventing spring 16 from decompressing and causing needle 1 to retract into the container. An illustration of the needle assembly in this configuration is shown in Fig. 5. This has the great advantage that one may expose a sheathed needle

without having to position one's fingers near the needle itself, as is done when exposing the sheathed needle described by Strauss (vide supra). When it is desired to retract the needle, 16 reversibly pushes pin 7 along slot 10 pin 7 out of slot 10a, and then spring.

As shown in Figs. 1 through 5, slot 10a is a simple transverse slot which intersects slot 10 at a right angle. While this is an effective arrangement, other configurations of slot 10a are possible. Three such arrangements are shown in Figs. 6a through 6c. In Fig. 6a, slot 10a is configured as a T-shaped notch. This T-shaped notch comprises a first transverse leg 10d which intersects slot 10, and a second leg 10e which intersects the transverse leg and is substantially parallel to slot 10. If desired, transverse leg 10d and leg 10e may be configured as an L-shaped notch, as shown in Fig. 6b. The notches of Figs. 6a and 6b operate in the following manner. Hub 2 is moved forward within the container until pin 7 reaches end 12 of slot 10. At this point, the needle is rotated by pushing pin 7 into transverse leg 10d of slot 10a until the pin reaches the point where legs 10d and 10e intersect. At this point, spring 16 biases the hub 2 away from ridge 15, causing pin 7 to enter leg 10e of slot 10a. Leg 10e acts as a stop, preventing spring 16 from decompressing further and causing needle 1 to retract into the container. Leg 10e also prevents the user from accidentally pushing pin 7 out of slot 10a.

In Fig 6c, slot 10a is configured as a C-shaped slot, where a first end of the C-shaped slot intersects slot 10 at point 12, and a second end 10d lies in line with slot 10. The end of slot 10 is separated from the second end of slot 10a by tab 24. The C-shaped configuration of slot 10a operates in the following manner. Hub 2 is moved forward

within the container until pin 7 reaches end 12 of slot 10. At this point, the needle is rotated by pushing pin 7 along slot 10a until it reaches end 10d. At this point, spring 16 biases the hub 2 away from ridge 15, pressing pin 7 against tab 24. Tab 24 acts as a stop, preventing spring 16 from decompressing further and causing needle 1 to retract into the container.

Notch 10b, which intersects longitudinal slot 10 near the first end of the container, also functions as a locking mechanism. When the needle is retracted into the container, pin 7 is adjacent to slot 10b. Pin 7 may then be pushed sideways into slot 10b so as to hold the needle assembly in the retracted position. Like slot 10a, slot 10b may be a straight transverse slot, a C-shaped slot, an L-shaped slot, or a T-shaped slot. Notches 10a and 10b are each wide enough to receive the pin engaged by the longitudinal slot. To retain pin 7 in notch 10a or in notch 10b when the needle is in use, each notch may be provided with teeth 200 which are spaced sufficiently closely together that the pin may not be pushed into, or out of, the notch without the deliberate application of force. A pair of such teeth are shown in the entrance to notch 10b in Fig. 7.

As shown in Fig. 6d, the means for reversibly locking the needle assembly in its exposed position may comprises a pair of teeth 200 on opposite sides of the longitudinal slot, said pair of teeth being positioned near a posterior end of the tubular sheath. No intersecting slots are required. A locking position is defined between the teeth and the posterior end of the longitudinal slot. The teeth cause the width of the slot to narrow to a width which is smaller than the diameter of the radially projecting member, but large

enough to allow a user to push the radially projecting member through the teeth. A similar mechanism for reversibly locking the needle assembly in its retracted position comprises a pair of teeth on opposite sides of the longitudinal slot, said pair of teeth being positioned near an anterior end of the tubular sheath. Alternatively (Fig. 6e), teeth 200 may be positioned on opposite sides of a slot 10a which intersects slot 10 at a right angle.

As shown in Fig. 6f, the means for reversibly locking the needle assembly in its exposed position may comprises a first hook 220a which engages the radially projecting member 7, and the means for reversibly locking the needle assembly in its retracted position may comprise a second hook 220b (not shown in Fig. 6f) which engages the radially projecting member. The first hook is located at the posterior end of the longitudinal slot, and the second hook is located at the anterior end of the longitudinal slot. If radially projecting member 7 is substantially longer than it is wide (Fig. 6g), a notch 7a in an edge of member 7 may be used to assist in engaging a hook 220a or 220b. The hook fits into the notch 7a, stabilizing the position of the radially projecting member.

Preferably, since used syringe needles may be biohazards, the retractable syringe needle also includes a mechanism for irreversibly engaging the pin near the first end of the container so as to retain a used needle in the retracted position. One version of the irreversible locking mechanism comprises a third notch 10c which intersects longitudinal slot 10 so that slots 10b and 10c are collinear, extending from opposite sides of slot 10 (Fig. 7). Slot 10c is wide enough to receive the pin engaged by the longitudinal slot, and comprises a pair of flexible projections 10f extending from opposite sides of slot 10c. The

projections have tips which contact each other, said tips being adapted to allow the pin engaged by the slot to pass therethrough when the pin enters the slot 10c from longitudinal slot 10, and to not allow the pin to pass therethrough to exit slot 10c. Each of the flexible projections makes an acute angle with the wall of slot 10c, and each of the flexible projections is directed away from the longitudinal slot 10. The pin 7 can pass between the projections as it enters slot 10c (Fig. 8b), but it cannot exit slot 10c between the projections (Fig. 8c). Projections 10f are able to bend away from slot 10 so as to allow pin 7 to pass therethrough and enter 10c, but they cannot bend toward slot 10 so as to allow pin 7 to exit 10c. If desired, one or more teeth 200 may be positioned in notch 10c between the opening to notch 10c and projections 10f, although they are not required for proper functioning of the retractable syringe. Teeth 200, if present, are designed so that the pin may be reversibly pushed into notch 10c through the deliberate application of a force having at least a first defined magnitude. The projections 10f are preferably designed so that force of the first defined magnitude F_1 is insufficient to force pin 7 through projections 10f. Force of a second defined magnitude F_2, greater than the first defined magnitude, is required to force pin 7 through projections 10f. Thus, the pin may be reversibly locked into notch 10c by pushing it into notch 10c with a force F, where $F_1 \leq F < F_2$; and the pin may be irreversibly locked into notch 10c by pushing it into notch 10c with a force of F_2 or greater. It is possible to omit notch 10b from the container structure entirely, and use notch 10c for both reversibly and irreversibly locking pin 7 into position. This is, however, much preferred to use notches 10b and 10c as separate locking mechanisms, due to the possibility of unintentionally irreversibly locking pin 7 into notch 10c when attempting to use notch 10c as a reversible lock.

A second version of the mechanism for irreversibly engaging the pin in its retracted position, shown in Figs. 9a and 9b, comprises a radially-directed peg 300, said radially-directed peg being mounted on an exterior surface of the tubular sheath 9 so that one end of the radially-directed peg is adapted to be pushed inwardly through a hole 301 in the wall of the tubular sheath and through a hole 302 in the tubular sleeve 3. The radially directed peg may be mounted to the tubular sheath by means of a tubular mount 304 having a bore with a diameter that corresponds to the maximum outer diameter of peg 300 so that peg 300 slides axially within mount 304. Mount 304 is mounted to the side of sheath 9 so that the axis of the bore of the mount is normal to the axis of sheath 9, and so that the bore of mount 304 is positioned above hole 301 in sheath 9. Mount 304 may be secured to sheath 10 directly, or by means of a cap 305, as shown in Figs. 9a and 9b. Cap 305 has a hole 305a therethrough, with this hole being in line with holes 301 in the tubular sheath. When pin 7 enters slot 10b and reversibly secures the needle assembly in a retracted position, hole 302 through the tubular sleeve in the needle assembly is brought into alignment with holes 305a and 301 (Fig. 9c; peg 300 omitted for clarity). Thus, after reversibly locking the needle in its retracted position, peg 300 can be simultaneously pushed through holes 305a, 301, and 302, preventing movement of hub 2 relative to sheath 9. If the needle has not been reversibly locked, hole 302 is not aligned with holes 305a and 301, preventing peg 300 from engaging hole 302 in the tubular sleeve (Fig. 9d; peg 300 omitted for clarity). Holes 305a and 301 may have a larger diameter than hole 302. Preferably, a stop 306 on peg 300 limits the depth to which peg 300 can enter sleeve 3. The outer diameter of stop 306 is greater than the diameter of hole 302. After the end

of the radially-directed peg 300 is pushed through hole 302, peg 300 may not be withdrawn through the hole in the tubular sleeve. This is due to flexible projection or projections 303, which project radially from peg 300. Projections 303 are angled toward stop 306, and away from the axis of sheath 9. Before peg 300 is pushed through holes 305a, 301, and 302 (Fig. 9b, the unlocked configuration), projections 303 are restrained to lie against peg 300 by the wall of mount 204. After peg 300 is pushed through hole 302 (Fig. 9a, the locked configuration), projections 303 are no longer restrained and extend radially. Since they are angled toward the interior of the wall of sleeve 3, projections 303 cannot be readily be folded away from the wall of sleeve 3. This makes it difficult or impossible to withdraw peg 300, resulting in a permanent lock.

Mount 304 will now be described in more detail. Mount 304 preferably is manufactured as a first inner cylindrical tube 304a and an outer cylindrical tube 304b. Tube 304a has an inner diameter which is equal to the diameter of holes 301 and 305a. Tube 304b has an inner diameter which is equal to the outer diameter of tube 304a, and an inwardly projecting flange 304c at one end. Flange 304c defines a hole 304d having a diameter which is large enough to allow the outer end of peg 300 to reversibly slide therethrough, but which is small enough to prevent stop 306 from passing therethrough. An exploded view of this construction is shown in Fig. 9f. Tubes 304a and 304b are preferably ultrasonically welded to ring 305. If a simplified construction is desired, tube 304a may be omitted and the inner diameter of tube 304b may be set to be equal to the diameter of holes 301 and 305a. This allows mount 304 to be constructed from a single piece.

If desired, projection 303 may take the form of a frusto-conical tube made of a flexible material (Fig. 9e). The narrow end of the frusto-conical tube is rigidly fixed to the inwardly directed end of peg 300. The frusto-conical tube is coaxial with peg 300, and surrounds the inwardly directed end of peg 300, with the proviso that the overall length of the frusto-conical tube is less than the distance between the inwardly directed end of peg 300 and stop 306. When peg 300 is simultaneously pushed through holes 305a, 301, and 302, the sides of the frusto-conical tube collapse against the side of peg 300. After the peg and the frusto-conical tube attached thereto are pushed through hole 302, the sides of the frusto-conical tube expand. Since the large end of the frusto-conical tube has a diameter that is greater than the diameter of hole 302, peg 300 may not be withdrawn through the hole in the tubular sleeve.

In an alternative embodiment, projections or tube 303 may be rigid and non-flexible. If 303 is non-flexible, hole 302 should have a smaller diameter than the maximum diameter of tube 303 or the maximum distance across projections 303. After the projections or tube 303 penetrate hole 302, the upper ends of projections or tube 303 act as stops to prevent the peg 300 from being withdrawn through the hole in the tubular sleeve.

A third version of the mechanism for irreversibly engaging the pin at the second defined location in said longitudinal slot so as to hold said needle assembly in a position where the needle is retracted within the container is provided. This version of the

mechanism features the rigid ring 9a mounted on wall 9 of the container; and a rigid tongue 9b attached to one end of the rigid ring by a living hinge 9c (Fig. 10a). This tongue is positioned so that it extends from the end of the container with syringe barrel-receiving opening 13. The second end of the rigid ring is substantially flush with one side of the slot 10b, without blocking slot 10b (slot 10c is not present in this embodiment). To permanently lock the needle assembly in a retracted position, pin 7 is moved into slot 10b, exactly as for the procedure for reversibly locking pin 7 into position. The rigid tongue is folded in the direction of arrow A against the external surface of the ring and irreversibly secured against the external surface of the ring so that the end of the rigid tongue blocks the opening of slot 10b while pin 7 is inside slot 10b. To accomplish this, the tongue is preferably designed so that it is collinear with slot 10 when it is in its initial, unfolded state, and has a length which is at least equal to the sum of the longitudinal length of the rigid ring and the width of slot 10b. To secure the tongue against the external surface of the ring, a hook 9d on the rigid tongue irreversibly snaps around the second end of the rigid ring (Fig. 10b). Hook 9d also blocks the opening to slot 10b. Alternatively, a post 9e on the rigid tongue may irreversibly snap into a hole 9f in the external surface of the rigid ring (Fig.10c). A projection on the end of the rigid tongue fits into slot 10, blocking the opening to slot 10b (Fig. 10d).

One difficulty in manufacturing an article of this type lies in the difficulty in getting the pin on the needle assembly to properly engage slot 10. For example, the invention of D'Amico (vide supra) presents a substantially cylindrical hub having a radially protruding pin attached thereto positioned within a tubular container. The inner circumference of the

container is substantially the same as the outer circumference of the hub. The pin is positioned within a slot in the wall of the container, where each end of the slot is closed. However, this article is difficult to manufacture inexpensively. When the hub slides into the container, the radially protruding pin is blocked by the end of the tubular container wall, and cannot readily enter the container.

This invention attempts to solve this problem. When the container is manufactured in one piece with a slot 10 which is closed at both ends, the combination of pin 7 and crosspiece 8 will not pass through slot 10 when the needle assembly of Fig. 1a is positioned inside the container of Fig. 2. To overcome this difficulty, one can position the needle assembly inside the container prior to attaching pin 7, and then insert pin 7 through slot 10 and secure the pin to sleeve 3. Alternatively, the container may be manufactured in two pieces, a tubular container and rigid ring 9a.

The retractable syringe needle of the current invention may be made by obtaining a needle assembly as previously described, and obtaining the previously-described container having a tubular wall 9 with an open-ended longitudinal slot 10 therein (Fig. 11). A spring or other biasing means is then inserted into the container. The needle assembly is then inserted into the syringe barrel-receiving end of the container so that pin 7 enters the open end of slot 10, and is slidably engaged by the longitudinal slot. The biasing means engages the hub of the needle assembly and reversibly biases the needle assembly toward a first position where the needle is concealed within the container. The rigid ring is then

mounted on the container so that the ring closes the open end of slot 10, preventing the pin 7 from exiting slot 10.

A second, and less preferred, method of solving the problem involves formation of the container in two parts, as shown in Fig. 12. The container is formed from an anterior portion 20 and a posterior portion 21. Anterior portion 20 has a first open end adapted to receive a syringe barrel and a second open end adapted to receive a hypodermic needle. Ridge 15 is positioned on the interior surface of the wall of anterior container portion 20. A first longitudinal slot 22 runs from the first end of the anterior portion of the container to point 12, near the second end of the anterior portion of the container. Slot 10a meets slot 22 at a right angle. Posterior portion 21 of the container has a first open end adapted to receive a syringe barrel and a second open end adapted to receive a syringe barrel. A second longitudinal slot 23 runs from the first end of the posterior portion of the container to point 11, near the second end of the posterior portion of the container. The first end of 20 and the first end of 21 are adapted to be joined together to form the complete container, by attaching 20 and 21 together so that slots 22 and 23 cooperate to form slot 10.

The manner in which 20 and 21 are joined together is not particularly limited. Parts 20 and 21 may be bonded together by means of a biocompatible adhesive. Alternatively, threaded ends on 20 and 21 may be screwed together, and then secured with a suitable adhesive. Also, a ridge on an interior surface of one piece may snap into a groove on an exterior surface of another piece. The ridge may be treated with an adhesive

prior to snapping it into the groove. Finally, if 20 and 21 are made from a thermoplastic material (i.e., polyolefin), they may be heat-sealed together. In the embodiment illustrated in Fig. 12, a threaded end 20a on container portion 20 is screwed onto a threaded end 21a on container portion 21.

The complete assembly is manufactured in the following manner, shown in Fig. 13. A spring 16 and the needle assembly are joined together by joining a first end of the spring to ridge 5 on hub 2. The needle 1 is positioned along the helical axis of the spring. This assembly is then positioned within the anterior portion 20 of the container so that a second end of the spring engages ridge 15. Container portion 20 is then joined to container portion 21 so that:

a) slots 22 and 23 line up to form slot 10; and

b) pin 7 is slidably engaged by slot 10.

Alternatively, hub 2 may be positioned within posterior portion 21 so that pin 7 engages slot 23, and then part 20 may be joined to part 21 of the container so that the second end of the spring engages ridge 15. Again, when joining pieces 20 and 21, care should be taken to ensure that slots 22 and 23 are aligned so as to form a single slot 10 which engages pin 7.

This assembly method allows the safety needle to be assembled quickly and easily, and avoids the difficulty of trying to position the needle inside a fully assembled container without damaging the pin by forcing it past the rim of the container.

Figs. 14 and 15 illustrate use of a syringe assembly with the safety needle of Fig. 3. The syringe comprises a syringe barrel 17, and a syringe plunger 18 slidably mounted therein. Barrel 17 has a frusto-conical tip 19 adapted to enter cavity 6 of sleeve 19 (cavity 6 is not shown in Figs. 5 and 6, as it is occupied by tip 19.). Tip 19, after insertion into cavity 6, frictionally engages the interior of sleeve 3, forming a leakproof seal. A hole in tip 19 receives fluids which have passed through the bore of needle 1.

As shown in Fig.15, syringe barrel 17 may be used to push the needle assembly within the container toward the second end of the container, compressing the spring and causing needle 1 to emerge through hole 14. In this position, the container encases at least a portion of barrel 17. Barrel 17 may then be rotated, causing sleeve 3 to rotate. This causes pin 7 to enter slot 10a, locking the syringe needle into position. The assembled syringe, with the needle exposed, may then be used to take a sample of a fluid. More particularly, the assembled syringe may be used to administer an injection to a patient, or to take a sample of arterial or venous blood from a patient.

After use, the contaminated needle may be discarded by rotating barrel 17 in the reverse direction to free pin 7 from slot 10a. This allows spring 16 to decompress, causing the container to slide forward off of the syringe barrel and cover needle 1. The

syringe barrel may then be separated from sleeve 3, and the container with the needle concealed therein may be discarded with minimal risk of injury from contact with the contaminated needle. The syringe barrel and plunger may be discarded, or sterilized in an autoclave for reuse.

As shown in Fig. 16, it is possible to secure two pins 7, each having a crosspiece 8 mounted thereto, on a single needle assembly, where the two pins are directed in opposite directions. Such a needle assembly may be mounted in a container having two slots 10a in opposite sides of wall 9. A transverse slot 10a intersects each slot 10, with each slot 10a running in the same direction (i.e., either clockwise or counterclockwise, when viewed from the second end of the container along the container axis). This version of the apparatus operates in the same manner as the assembled apparatus of Fig. 3. The only difference is that the presence of the second pin anchors hub 2 of the needle assembly more firmly along the axis of the container (Fig. 17).

Fig. 18 shows an alternative embodiment of the needle assembly of Fig. 1a. This embodiment of the needle assembly features a hollow straight needle 29 having two ends. The needle 29 extends through a hub 30, so that a first end of the needle 29a points in a forward direction, and a second end of the needle 29b points in a reverse direction. Pin 7 is rigidly connected with said hub, and extends in a radial direction. Crosspiece 8 is connected with the pin at a defined distance from the hub. Preferably, a rubber sheath 31 covers end 29b of needle 1.

Fig. 19 shows the needle assembly of Fig. 18 mounted within a container similar to that of Fig. 2. The container features a defined cylindrical axis and has a tubular wall 9 with a longitudinal slot 10 therein. A first open end of the container is adapted to receive a receptacle for venous blood, preferably an evacuated test tube with a rubber stopper, and a second open end adapted to allow the first end of the hollow needle to pass therethrough. The longitudinal slot extends from the first open end of the container to a defined point near the second open end of the container, where the longitudinal slot is open-ended at the first open end of the container and closed at the second open end of the container. A rigid ring is positioned over the first open end of the container so as to close the open end of the longitudinal slot. A plurality of circumferential strengthening ridges may be positioned on the exterior surface of the container. The needle assembly is mounted within the container so that (i) the first end of the needle, 29a, is directed toward the second open end of the container, and (ii) pin 7 on the needle assembly is slidably engaged by longitudinal slot 10, with crosspiece 8 acting to support hub 30 so that it is positioned on the axis of the container. End 29a of needle 29 is exposed by using the thumb or finger to manually slide piece 8 forward toward needle-receiving opening 14, carrying hub 30 toward the second end of the container until the needle end 29a passes through opening 14 and is exposed. Piece 8 is then pushed sideways until pin 7 enters slot 10a, locking the needle into the exposed position. The needle may then be inserted into a patient's blood vessel. The rubber sheath prevents the patient's blood from traveling through the needle. Positioned inside the container, there is a spring or other means for biasing the needle assembly towards a position where the needle is concealed inside the container; the biasing means acts to prevent premature exposure of the needle.

The double-ended safety needle additionally features a first notch 10a which intersects the longitudinal slot at a first defined location near the needle-receiving opening 14 in the container. The needle may be reversibly secured in an exposed position by pushing pin 7 toward opening 14 until pin 7 is positioned adjacent to notch 10a, and then pushing pin 10b sideways into notch 10a. The biasing means presses the pin against the rear wall of notch 10a, securing the needle assembly into position. Similarly, the needle may be reversibly secured in a concealed position by pushing pin 7 toward opening 13 until pin 7 is positioned adjacent to a second notch 10b near opening 13 in the container, and then pushing pin 10b sideways into notch 10b. As previously described, each of notches 10a and 10b may be straight transverse notches, or notches 10a and 10b may each independently be a T-shaped notch (as seen in Fig. 6a), a L-shaped notch (Fig. 6b), or a C-shaped notch (Fig. 6c). Also, each notch may be provided with teeth 200 which are spaced sufficiently closely together that the pin may not be pushed into, or out of, the notch without the deliberate application of force.

A means for irreversibly engaging the needle assembly in a retracted position comprises a third notch 10c, where notches 10b and 10c are collinear and extend in opposite directions from the longitudinal slot as seen in Figs. 7 and 8. A pair of flexible projections having tips which contact each other extend from opposite sides of notch 10c. The tips are adapted to allow the pin engaged by the slot to pass therethrough when the pin enters notch 10c from the longitudinal slot, and to not allow the pin to pass therethrough to exit notch 10c.

Alternatively, the means for irreversibly engaging the pin may comprise a radially projecting peg 300 which is secured to the rigid ring by a tubular mount 304, substantially as seen in Figs. 9a and 9b. The tubular mount preferably takes the form of a cylinder having a defined axis, where the defined axis of the cylinder is directed radially outward from the surface of the housing. The rigid ring is positioned so that one end of the rigid ring is substantially flush with one side of notch 10b (no notch 10c is present in this embodiment). To secure the pin in notch 10b, the peg is pushed through a series of coaxial holes 305a, 301, and 302, through the ring, the sheath 9, and the sleeve 3, respectively. Projections 303 on peg 300 then spread out and prevent peg 300 from being withdrawn through hole 302, effectively locking the needle assembly in place, relative to sleeve 9. The peg must be short enough that it will not interfere with the rearwardly projecting end of the hollow needle.

Additionally, the means for irreversibly engaging the pin may comprise a rigid tongue attached to one end of the rigid ring by a living hinge, as seen in Figs. 10a through 10d. The rigid ring is positioned so that the other end of the rigid ring is substantially flush with one side of notch 10b (no notch 10c is present in this embodiment). To secure the pin in notch 10b, the rigid tongue is folded against an external surface of the ring and irreversibly secured against the external surface of the ring so that the end of the rigid tongue blocks the opening of the second notch.

To hold the rigid ring in position relative to the wall of the container, a circumferential ridge 9g on the interior surface of the rigid ring 9a snaps into a circumferential groove 9h on the exterior surface of the container (Fig. 20). Also, a ridge 9i on the interior of the rigid ring may fit into the open end of slot 10 to prevent rotation of the ring relative to the slot.

The assembly of Fig. 19 may be used with a receptacle for receiving a blood sample, as shown in Fig. 21. This receptacle is a test tube 32 having an open end. A rubber septum 33 seals the open end of the test tube. The interior of the test tube may be under vacuum. While needle 29 is in the patient's blood vessel, the end of the test tube which is sealed by septum 33 is inserted into opening 13 of the container until septum 33 contacts rubber sheath 31. The test tube is then pushed toward hub 30, and septum 33 pushes the end of rubber sheath 31 along needle 29 toward hub 30, exposing end 29b of needle 29. End 29b of needle 29 pierces the rubber sheath 31 and septum 33, entering the test tube. Blood from the patient then travels through hollow needle 29 into the test tube. After taking a sample of the patient's blood, test tube 32 is removed from the container. Rubber sheath 31 resumes its original configuration, covering end 29b of the needle and cutting off the flow of blood. Needle 29 is then withdrawn from the patient's blood vessel. Crosspiece 8 is then pushed sideways until pin 7 exits slot 10a, unlocking the needle. Spring 16 then causes needle 1 to withdraw into the container.

As in the syringe needle assembly of Fig. 3, piece 8 is sufficiently large that it cannot pass through slot 10 into the interior of the container, and is rigidly secured to a

defined position along the length of pin 7, where the defined position on pin 7 is chosen so that hub 30 of the needle assembly is positioned along the cylindrical axis of the container. More particularly, the distance between the axis of hypodermic needle 1 and crosspiece 8 is equal to the one half the external diameter of the wall 9 of the container. This retains needle 29 along the axis of the container.

The use of crosspiece 8 to retain needle 1 in position is particularly important in an apparatus for obtaining blood samples. The container has to be wide enough to receive the test tube, which in turn is normally wider than hub 2. Without crosspiece 8, pin 7 would slip out of slot 10, and end 29b of needle 29 would fall against the inner surface of wall 9. Needle 29b would then be incorrectly positioned to penetrate septum 33.

A threaded male joint 34 may surround opening 13 at the first end of the container of Fig. 2, and a threaded male joint 35 may surround opening 14 at the second end of the container. Cap 36 having a threaded female joint may be screwed onto joint 34, covering opening 13, and cap 37 having a threaded female joint may be screwed onto joint 35, covering opening 14. This is normally done whenever the needle is not intended to be exposed, so as to minimize the risk of accidental contact with the tip of the needle.

A further embodiment of the invention will now be discussed. This embodiment, shown in Fig. 22, features a hollow hypodermic needle 38 and a cylindrical hub 39 having an axial passage therethrough. The hollow needle is rigidly connected with the hub so that the axial passage and the interior of the hollow needle form a continuous conduit. Hub 39

is secured to one end of an adjustable-length tube 40 so that the interior of hollow needle 38 makes fluid contact with the interior of tube 40. The tip of a syringe barrel, which may be cylindrical or frusto-conical, may be frictionally secured to the other end of the adjustable-length tube so that the interior of the syringe barrel is in fluid communication with the interior of the adjustable-length tube. Tube 40 is preferably impermeable to liquids, non-elastic, and axially collapsible. By collapsing the tube in an axial direction, the length of tube 40 may be changed from a first extended length to a second contracted length. The tube may then be extended in an axial direction, restoring the length of the tube to the first extended length.

A tubular sheath 43 is disposed around the adjustable-length tube 40. The tubular sheath 43 has a first end 43a which is rigidly connected with the first end of the adjustable-length tube and a second end 43b having an opening 44 which is sufficiently large to allow the end of the hypodermic needle 38 to pass therethrough. The outer surface of member 51 is rigidly secured to end 43a of sheath 43. When the apparatus is not in use, the opening at each end of the tubular sheath may be covered by a cap (not shown in the drawings). The caps may screw onto the sheath, or snap onto the sheath.

The preferred means of connecting the adjustable-length tube 40 to sheath 43 is by means of a collar ring 40e which comprises an outer skirt 40f which fits over the outer surface of sheath 43 (Fig. 23c). The outer skirt is connected with an inner skirt 40g which fits inside sheath 43. A female joint 40h is rigidly connected with the inner skirt of collar ring 40e in such a way that a syringe barrel may be inserted into the inner skirt of collar

ring 40e and engage joint 40h. The inner and outer skirts of collar ring 40e are connected by a rigid ring 40i.

The retractable needle featuring the adjustable-length tube additionally features a means to alter the length of the adjustable-length tube from the contracted length to the extended length. This length-altering means includes a longitudinal slot running along the length of the tubular sheath; and a knob or pin 7 connected to the hub of the needle assembly. The knob or pin slidably engages the longitudinal slot, and may be used to change the length of the adjustable-length tube from its collapsed state to its extended state. The retractable needle additionally features a means for reversibly securing the knob at a first position along the length of the longitudinal slot, where the tube is contracted when the knob is in said first position; a means for reversibly securing the knob at a second position along the length of the longitudinal slot, where the tube is extended when the knob is in said first position; and a means for irreversibly securing the knob at said first position along the length of the longitudinal slot.

The structures of the reversible and irreversible securing means are substantially as previously described, with the following provisos. If the peg-based permanent locking mechanism of Fig. 9a is used, it is preferred that the sleeve 3 having hole 302 therethrough be coaxial with adjustable-length tube 40, with a gap which is sufficiently large to receive the end of peg 300 therebetween (Fig. 22a). That allows the peg 300 to penetrate hole 302, engaging sleeve 3, without allowing fluid flowing through the adjustable-length tube to escape through hole 302.

Also, one preferred mechanism for locking the needle in the exposed position for an embodiment using an adjustable length tube involves the use of an L-shaped slot 10a (Fig. 23a). The adjustable-length tube is extended, and radially projecting member 7 connected to hub 39 is pushed sideways into a transverse branch of slot 10a, and then backwards into the longitudinal branch of slot 10a. Although not necessary, a short spring may be attached to the hub or to the interior of the sheath 43, near end 43b having the opening for the needle. The spring acts to bias the hub, and radially projecting member 7 attached thereto, backwards, so that member 7 is pressed against the rear wall of the longitudinal branch of slot 10a. This holds the hub in position until the user is ready to retract the needle.

Alternatively, another preferred mechanism for locking the needle in the exposed position for an embodiment using an adjustable length tube involves the use of a slot 10a having teeth 600 (Fig. 23b). The gap between teeth 600 is less than the width of the radially projecting member 7, but is large enough the member 7 can be pushed between teeth 600. The adjustable-length tube is extended, and radially projecting member 7 is pushed sideways into slot 10a through teeth 600. The teeth act to prevent member 7 from accidentally leaving slot 10a, holding the hub in position. Member 7 can be pushed out of slot 10a through teeth 600 when the user is ready to retract the needle. No spring is required in this embodiment.

The preferred embodiments of the adjustable-length tube 40 will now be discussed. The most preferred type of adjustable-length tube 40 contemplated for use in this invention features a series of circumferential pleats 57 disposed along the length of the tube, as shown in Figs. 23a and 23b. When tube 40 is in its contracted or collapsed state (Fig. 24a), pleats 57 are folded together. The adjustable-length tube may be lengthened by pulling one end of tube 40 (the end to which the hub is attached) away from the other, causing pleats 57 to unfold (Fig. 24b).

Another embodiment of adjustable-length tube 40 is a telescoping tube made from an outer tube 40a and an inner tube 40b, as shown in Figs. 25a and 25b. The inner tube is slidably disposed within the outer tube. A first end of outer tube 40a is adapted to be secured to syringe barrel 40 through conical member 51, as previously described. A first end of inner tube 40b is adapted to be secured to hub 39. The inner tube 40b may be moved from a position where tube 40b is entirely or primarily disposed within tube 40a (Fig. 25a), contracting tube 40, to a position where tube 40b is mostly exposed (Fig. 25b), expanding tube 40. Ridges 40c on the interior of outer tube 40a interact with a ridge 40d on the outer surface of tube 40b, acting as stops to prevent removal of tube 40b from tube 40a. Preferably, a leakproof sealing material 58 is disposed between the outer surface of the inner tube and the inner surface of the outer tube. This sealing material may be a hydrophobic, biocompatible polymer with a low coefficient of friction, such as silicone or teflon.

When the adjustable-length tube is contracted, the hypodermic needle is entirely disposed within the sheath (Fig. 25c). When the adjustable-length tube is extended, the end of the hypodermic needle is exposed through opening 44 in the second end of the sheath (Fig. 25d). If desired, the interior diameter of the sheath 43 may narrow from a diameter which is great enough to receive the adjustable-length tube 40 to a diameter which is little greater than the diameter of needle 1. This narrowing occurs at a point 43c near the opening 44. When the needle is disposed within the sheath, the pointed end of the needle then occupies a position where the inner diameter of the container is small (Fig. 19a). This helps prevent the needle point from moving away from the axis of the container. If desired, a spring or other biasing means may bias the hub away from opening 44. This causes the adjustable-length tube to preferentially occupy its contracted state, with the needle being retracted within the container.

Preferably, the adjustable-length tube is connected to the syringe barrel by means of an adaptor 500. The adaptor fits inside the end of sheath 43, and is rigidly connected to the adjustable-length tube. The adaptor further includes a cavity 501 adapted to frictionally engage the end of a syringe barrel. This cavity is in fluid communication with the interior of the adjustable-length tube. A collar ring 502 is secured to the end of adaptor 500 in such a way that a gap 503 is defined between an exterior surface of the adaptor and an interior surface of the ring 502. The end of sheath 43 then slides into this space 503, and is rigidly secured to the exterior surface of the adaptor and/or to the interior surface of the ring 502.

This embodiment of the invention may be used to withdraw fluid samples from a patient's bloodstream, or to inject medicinal fluids into a patient's bloodstream. A syringe barrel 41 having a plunger 42 slidably mounted therein may be reversibly secured to the other end of the adjustable-length tube 40 so that the interior of the syringe barrel is in fluid contact with the interior of the adjustable-length tube, as shown in Fig. 26. By raising the plunger and creating a partial vacuum within barrel 41, fluids may then be drawn through needle 38 (not shown in Fig. 26) and tube 40 into barrel 41. The syringe barrel 41 is secured to the first end of the adjustable-length tube 40 by means of a hollow conical member 51. The inner surface of member 51 defines a cylindrical or frusto-conical cavity 52 adapted to frictionally engage the tip 41a of the syringe barrel. The conical member 51 has a passage 51a therethrough. Member 51 is connected to the end of the adjustable-length tube 40 to which hub 39 is not secured. The cavity 52 makes fluid contact with the interior of the adjustable-length tube 40 through the passage 51a. As the outer surface of member 51 is rigidly secured to the first end of the tubular sheath 43 (sheath 43 is not shown in Fig. 21), sheath 43 is immobile relative to a syringe barrel 41 connected to tube 40.

A needle assembly for use with a catheter is assembled as shown in Fig. 27. Hollow needle 100 extends from one end of a cylindrical hub 101, and penetrates the second end of the hub. The second end of the hub is connected to a flash chamber 102 which features a tubular side wall 103 having a first end which makes a watertight seal with the second end of hub 101. A small plug of absorbent material 105, such as cotton, is normally present in flash chamber 102, and closes the second end of tubular wall 103,

preventing leakage of fluids from the flash chamber. The interior of flash chamber 102 is in fluid communication with the interior of hollow needle 100, so that fluid may travel through the needle 100 into chamber 102. The tubular wall of chamber 102 is normally transparent or translucent, so that blood entering the flash chamber through needle 100 is readily visible. A stem 106 protrudes radially from hub 101. A thumbrest 107 is attached to stem 106. A sleeve 104 may project from the end of the flash chamber opposite to needle 100; this sleeve may have a radially directed hole 104a therethrough. The needle assembly having the flash chamber is positioned inside a container with a defined cylindrical axis having a tubular wall 9 with a longitudinal slot 10 therein. The container has a first end having an opening 109 adapted to allow the hollow needle to pass therethrough and a closed second end. A tubular extension 110 of the container surrounds opening 109. Additionally, a pair of finger rests 400 is positioned on opposite sides of the container, with slot 10 running therebetween (Fig. 30). The finger rests 400 are useful for gripping wall 9 of the container when inserting the needle into a patient. The pin of the needle assembly is slidably engaged by the longitudinal slot in the container, so that said needle assembly may be moved from a first position where the needle is within the container to a second position where the needle is exposed by sliding the pin toward the first end of the container. A spring 108 reversibly biases the needle into the first position. A notch 10a may be used to reversibly retain the needle in an exposed position, while a notch 10b may be used to reversibly retain the needle in a retracted position, exactly as previously described. A means for irreversibly retaining the needle in its retracted position may comprises a third notch 10c, where notches 10b and 10c are collinear and extend in opposite directions from the longitudinal slot. A pair of flexible projections having tips

which contact each other extend from opposite sides of the third notch, directed away from slot 10. The projections allow the pin engaged by slot 10 to pass therethrough when the pin enters notch 10c from the longitudinal slot, and to not allow the pin to pass therethrough to exit notch 10c (Figs. 7 and 8). Alternatively, the container may comprises a housing having a first open end adapted to admit the needle assembly and a second open end adapted to admit the hollow needle, and a cap 9a at the first open end of the housing. The longitudinal slot extends from the first open end of the housing to a defined point near the second open end of the container, said longitudinal slot being open-ended at the first open end of the container and closed at the second open end of the container. Cap 9a blocks the open end of the longitudinal slot. The cap has a skirt that extends over the exterior of the housing until it reaches the edge of the first notch. Cap 9a may also serve to close the opening at the first open end of the housing. However, this is not necessary; cap 9a may leave an opening allowing access to the interior of the housing.

The needle for use in catheter insertion further comprises a means for permanently locking the needle in a retracted position. For example, a rigid tongue may be attached to the cap by a living hinge. After pin 7 is positioned in slot 10b, the rigid tongue may be folded against the skirt of the cap and irreversibly securing against the external surface of the skirt so that the end of the rigid tongue blocks the opening of 10b, preventing pin 7 from exiting notch 10b, exactly as previously described (Figs. 10a through 10d). Alternatively, the means for irreversibly engaging the pin may comprise a radially projecting peg 300 which is secured to the cap 9a by a tubular mount 304, substantially as seen in Figs. 9a and 9b, where cap 9a takes the place of 305. To secure the pin in notch

10b, the peg is pushed through a series of coaxial holes 305a, 301, and 302, through the cap 9a, the sheath 9, and a sleeve secured to the flash chamber, respectively. The sleeve is secured to the opposite end of the flash chamber from the hub. Projections 303 on peg 300 then spread out and prevent peg 300 from being withdrawn through hole 302, effectively locking the needle assembly in place, relative to sleeve 9. Alternatively, the means for irreversibly engaging the pin may comprise a radially projecting peg 300 which is secured directly to sheath 9 by a tubular mount 304, with cap 9a being omitted. A bore through the tubular mount 304 is aligned with a hole 301 through the wall of sheath 9. Peg 300 may then be pushed through hole 301 in the sheath 9 and through hole 104a in the sleeve 104 attached to the catheter flash chamber, locking the retractable needle into position, substantially as previously described. The tubular sheath 9 has a constant internal diameter and the longitudinal slot 10 in the tubular sheath is open at the second end of the tubular sheath. The needle assembly is positioned in sheath 9 through the open end of sheath 9, with the pin 7(not shown in Fig. 29, for reasons of clarity) on the needle assembly entering the open end of slot 10 and slidably engaging the slot. A cover 307 fits over the second end of the tubular sheath and closes the longitudinal slot. The cover has an opening 308 which is large enough to allow the hollow needle to pass therethrough, but is too small to allow the hub of the needle assembly to pass therethrough. The cover has a skirt 309 that fits over the tubular sheath, said skirt having an external surface with a means for gripping the posterior end of the tubular sheath thereon. The gripping means may comprise two tabs 310 on opposing sides of the skirt.

When the retractable catheter needle is in its exposed position, a flexible catheter 111 having a longitudinal bore therethrough is supported by the needle 100 (Fig. 30). The tip of the needle is exposed through an opening at one end of the catheter. The other end of the catheter is adapted to fit over extension 110, reversibly securing the catheter in position. A knob or other gripping means 112 allows the user to grasp the catheter after it has been inserted into a patient. The needle may then be withdrawn from the catheter, with the catheter remaining in position in the patient. The needle is then retracted into the container. Normally, the catheter is initially provided in position on the needle, with a protective cap or sheath covering the needle and catheter.

For those embodiments of the invention described herein which are intended for use with a catheter, it is now proposed to describe the catheter 600 intended for use with this invention (See Fig. 31a and 31b). The preferred catheter 600 comprises a joint 601 adapted to fit onto a joint on the posterior end of the tubular sheath surrounding the needle assembly. The joint on the catheter may be a female joint adapted to frictionally engage a male joint on the tubular sheath, or the joint on the catheter may be adapted to engage a joint on the tubular sheath by means of a Luer-Loc® connection. The joint on the catheter is connected with a first end of a hub 602 having a longitudinal bore 603 therethrough. A second end of the hub is connected with a cannula 604 having a longitudinal bore therethrough, where the bore of the cannula is in fluid communication with the longitudinal bore of the hub. When the hub of the catheter is connected to the joint on the tubular sheath, the bore of the cannula is also in fluid communication with a longitudinal bore in the joint on the posterior end of the tubular sheath. The hub of the

catheter additionally features a tranverse bore 605, which intersects the longitudinal bore therethrough. A stopcock 606 having a transverse bore 607 is fitted into the bore 605. A handle 608 on the stopcock allows the user to rotate the stopcock between a first open position (Fig. 31c), which allows the flow of fluid through bore 603, and a second closed position (Fig. 319) that blocks the flow of fluid through bore 603.

Referring now to Figures 32a, 32b, and 32c, the sheath 9 is shown having three different embodiments of the longitudinal slot 10. The operation of each of these embodiments will be explained in full below. In figure 32a, the slot 10 terminates in a cross slot 10a which extends along the outside wall of the sheath 9. Slot 10 a then turns 90 degrees to form a short second longitudinal portion 10b in the anterior direction.. In Figure 32 b, the longitudinal slot 10 also has a cross slot portion 10a. However, in this embodiment, the cross slot 10a terminates in a round portion 10c. The diameter of the round portion 10c is sized to be a tight fit with the diameter of the post 7 when the post 7 is rotated to engage the cross slot.. In Figure 32c, the longitudinal slot 10 is tapered at the posterior end such that the post 7 will wedge tightly in the slot when the needle is in the exposed position.

The means for reversibly locking the needle assembly is basically the same as described above in connection with Figures 11-17. However, the cross slot shown in Figure 32a may be used instead of the plain slot of Figures 11-17. To reversibly lock the needle in the exposed position using the cross slot of Figure 32a, the post 7 attached to the cross piece 611, is moved to the posterior end of the longitudinal slot 10 and then

rotated along the cross slot 10a. When the post reaches the second longitudinal slot 10b, the spring 16 draws the post 7 into the short slot 10b locking the needle in the exposed position. To reversibly lock the needle in the exposed position using the embodiment of Figure 32b, the post 7 is again moved to the posterior end of the longitudinal slot 10. The post 7 is rotated along the cross slot 10a to the round portion 10c. The round portion 10 c is formed to provide a tight fit with the diameter of the post 7. When the post 7 reaches the round portion 10c, the post is forced past the restricted portion 10d .and clicked into the round portion 10c. In this position, the needle assembly is locked in the exposed position until the post 7 forced out of the round portion and returned to the longitudinal slot to return to the anterior end of the sheath. When this reversible locking means is used the spring 16 is not required.

Referring now to Figures 33a, 33b, and 33c, and 32d, there are illustrated various means for reversibly locking the needle in the exposed position or the reversible retracted position. In Figure 32a, the sheath 9 is shown with its longitudinal slot 10 terminating at the posterior end in a cross slot 10a connected to a short longitudinal slot 10b. In Figure 32 b, the reversible locking slot at the posterior end of the sheath terminates in a round opening sized to fit the diameter of the post member described below. At the anterior end of this sheath and the sheath of Figure 32a second cross slot 10a is provided. However in this cross slot teeth 200 are provided to engage the post of the sliding mechanism and reversibly lock the post in the retracted position. When a reversible locking provision is required, the cover 609 is provided with a lateral opening, 609' (in Figure 34d,) to allow the post to be rotated into the reversible locking slot at the anterior end of the sheath.

The body of the device of this invention is completed by the attachment of a cap 9a at the anterior end of the sheath. The importance of the cap will be shown in the following description.

Figures 33a and 33b, there is illustrated an embodiment for permanently locking the needle assembly in the retracted position In this configuration, the post 7 and its attached cross piece 611 with its attached needle assembly are moved to the anterior end of the slot 10. A pin 614 is attached to the cap 9 and protrudes above the cap outer surface. As shown, the pin may has a tapered upper surface however the pin may be configured with a flat top surface. As the post slides into the slot 620 in the cap 9, the tapered bottom surface the cross piece 612 slides over the post 614. When the opening 612 in the cross piece is centered on the post 614, the cross piece drops over the post thus locking the needle in the retracted position as shown in Figure 33b. The cover 609 over the pin 614 prevents access to the cross piece after the permanent locking procedure is completed thus preventing moving the needle back into the exposed position.. In figure 33c, the hole 612a is a blind hole closed at its top surface and in Figure 33d, the hole 612 is a similar blind hole having a hemispherical shape. In this case the pin 614 would be formed in a complementary hemispherical shape. This feature enhances the security of the device by preventing access to the locking feature of the device. A plan view of this embodiment is shown in Figure 33d. In this embodiment the cap 9a serves as the attachment point for the permanent locking mechanism and cover. Here, the cap is open at its anterior end to allow a syringe to be inserted and connected to the hub 3 of the needle assembly A spring 16 is provided as before which biases the needle assembly in the direction of the anterior end when it is compressed.

Referring now to Figures 34 a and 34b, there is shown a further embodiment of the mechanism for permanently locking the needle in the retracted position. In this embodiment, the crosspiece 608, attached to the needle by post 7, is provided at its anterior end with a downwardly formed hook 608a. This hook is formed at approximately 90 degrees to the upper surface of the cross piece 608. On the cap 9a of the sheath 9 there is provided, a flexible resilient ramp 610 under the cover 609. To lock the needle permanently in the retracted position, the cross piece attached to the needle is moved to the extreme anterior end of the longitudinal slot 10 in the sheath and into the slot 620 in the cap. The hook 608 rides on top of the ramp 610 depressing it moving it downward until the hook 608a passes the anterior end of the ramp. At this point, the ramp springs up under the cross piece to its original position thus causing the hook 608a to trap the cross piece and needle permanently in the retracted position. A partial plan view of this embodiment is shown in Figure 34c.

When a reversible locking position is required, the cover member 609 , shown enlarged in Figure 34d. is provided with a lateral opening to allow the post 7 to enter the cross slot 10a and hold the needle reversibly locked in the retracted position in the manner described above. Reversible locking is achieved when the post 7 supporting cross piece is aligned with the slot 10b. The cross piece and needle are then rotated about the longitudinal axis of the sheath to move the post 7 into the slot 10b thus preventing the needle from moving to the exposed position until the user releases the lock formed by the slot 10b and the internal teeth 200.. The same provision applies to the embodiment of figure 33 .

Figure 34e shown an alternate embodiment of the device of Figure 34a. In this embodiment, the cross is supoplied with the sams hook 608a. However, in this embobiment, the ramp 610 has only a slightly upraised anterior end. However in this case, there is provided in the cap 9a a cavity 626 under the ramp 610. Here, when the cross piece 608 and its hook portion 608 passes over the ramp, it depresses the ramp onto the cavity 626 allowing the kook 608a to pass over the anterior end of the ramp. As in the previous embodiment, when the hook 608a the anterior end of the ramp 610, the ramp pops out of the cavity 626 and is trapped behind the hook 608a to achieve a permanent locking position for the needle assembly.

Referring now to Figures 35a through 35f, there is illustrated another embodiment of the invention which may be used to draw blood from a patient. This embodiment utilizes the principal features of the permanent locking mechanism illustrated in Figures 33 and 34. In this embodiment, a reversible locking mechanism is used only as a shipping lock or to place the needle in position for insertion. This reversible locking mechanism is the same as that illustrated at the posterior end of the sheath in Figures 32a,b and c. The needle 1 is in the extended position in the initial shipping lock condition. Figure 35b illustrates the shipping lock using the cross slots10a and 10b which forms an L shaped opening in the sheath wall. In order to protect the user, a removable cover 618 is placed over the needle 1 in the well known manner. The needle assembly is attached to the cross piece 611 as discussed in connection with Figures 33 and 34 however in this embodiment, the hub 3 shown in Figures 33 and 34 is changed to the cylindrical configuration shown at

624. The sheath 9 has a longitudinal slot 10 in which the cross piece and needle are free to slide. The cross piece 611 is provided with a butterfly wing-like gripping device 616 . In this embodiment one of the permanent locking devices shown in Figures 33 or 34 is provided on the cap 9 at the anterior end of the sheath 9 and operate in the same manner as described in connection with these last mentioned figures. Here, the needle1 is attached to a body member 624 which has a flexible tube 620 attached. This tube passes through the open anterior end of the cap 9a. At the distal end of the tube 620 , there is provided a connector member 622 illustrated in detail in Figures 35d and 35e. In Figure 35d, a frustro-conical opening is provided in the connector 622 to accommodate a syringe for drawing blood. In Figure 35e , a hollow needle 628 is attached to the tube 620. This needle is covered by a soft rubber sheath 630. This device is used in conjunction with a tube under a vacuum which is sealed by a rubber septum. The needle 1 is inserted through the septum after piercing the cover 630. The vacuum in the tube draws the blood into the tube. This process is illustrated in Figure 21 above. The operation of the device of Figure 35 is as follows. First the protective cover is removed from the needle. The needle is then inserted into the patient's blood vessel using the butterfly wing-like device 616. After the withdrawal is completed either by a syringe or a vacuumized tube , the cross piece and its attached needle are moved to the anterior end of slot 10 and the cross piece 612 is permanently locked in position and the assembly is ready to be discarded in the usual manner. Figure 35c illustrates another reversible locking means for the needle of this embodiment. Here the longitudinal slot 10 is tapered at its posterior end to a dimension slightly smaller than the diameter of the post 7. To use the device and for safe shipping, the post 7 is moved to the posterior end of the longitudinal slot 10 until it wedges in the

tapered portion of the slot . This wedging action creats a reversible locking means for the needle.

Referring now to Figure 36a, there is shown an embodiment of the invention used for inserting a catheter into the patient. The needle 1 is attached to a small flash container 627 in the sheath 9 and inserted through the catheter 630. The catheter and needle are covered by a removeable protector 634. A reversible locking mechanism is provided at the anterior end of the longitudinal slot 10. This reversible locking is provided by either the means shown in Figure 36c or the tapered slot of Figure 36b. The operation of these locking means is the same as discussed in connection with Figures 33 and 34 when like means are used. The operation of this device is described in detail in connection with Figures 27 and 28. However, in this embodiment, one of the permanent locking systems described in connection with Figures 33 and 34 is applied in order to permanently lock the needle is a retracted position for safe disposal. In this embodiment, the spring 16 is not required. Also, Since no reversible locking means is provided at the anterior end, the cover 609 will have solid walls on both sides and the anterior end forming a closed box having only its posterior end open. In addition, since no access is required from the anterior end of the device as it was in the previously described embodiments, the cap 9a is closed on its anterior end.

Referring now to Figures 37, 37a and 37b there is shown another embodiment of the invention described in connection with Figures 23a 23b and 23c. In this embodiment, a flexible tube is provided in the body of the device and it is connected to a needle 1 at the posterior end and terminates at a collar ring 40e. As discussed in connection with Figure

23, the end attachment in the collar 40e is adapted to engage a syringe. The Collar 40e replaces the cap described in connection with Figures 32,33 and 34. However, in this embodiment, the pin 614 of the permanent locking system is attached to the outer surface of the collar 40e at the anterior end of the longitudinal slot 10. The opening 612 in the cross piece 611 locks on the pin 614 when the cross piece 611 is moved to the extreme anterior end of the slot 10.

Figure 37a illustrates the permanent locking mechanism of Figure 33 applied to the embodiment of this Figure 37. Again, the ramp 610 is attached to the collar 40e and has its anterior end raised from the surface of the collar. The cross piece 608 ha a hook member 608a at its anterior end which lock over the anterior end of the ramp 610 when the cross piece is moved to the extreme anterior end of the longitudinal slot 10 after the cross piece depresses the ramp 610 and then releases it to return to its original raised condition under hook of the cross piece 608. Figure 37 b illustrates the hook locking system of Figure 34e, attached to the collar 40e instead of the cap 9a of Figure 34e.

In the alternate embodiment of Fig. 38, the sleeve is identified as sleeve 701 to which the needle 701 is attached. The sleeve 703 has a post 707 which includes a knurled top surface 708. The post 707 has a pin 709 including a ramp surface 710.

The sleeve 703 fits into a space 712 of a cap 714. The cap 714 includes a shoulder 716 which with the outer wall of the cap defines a space 718. The space 718 accommodates the upper part of the post 707 such that when the post 707 is inserted into the space 718, the ramp surface 710 of the pin 709 engages the surface 720 and is "squeezed" as it is inserted. The shoulder 716 includes an aperture 722 into which the squeezed pin 709 is injected due to the inherent spring force in the pin 709 due to the squeezed insertion. Once the pin 709 is received in the aperture 722 the sleeve 703 is locked .

The space 718 of the cap 714 includes at least one lateral wall 724 which partly defines the space 718. The side opposite to the lateral wall 724 either has no wall or a partial lateral wall. In Fig. 38 the opposite side is shown without a lateral wall. The opening defined by the lack of an opposite lateral wall , or only a partial opposite lateral wall permits the sleeve 703 to be rotated into a slot in the sheath 726, shown only schematically in Fig. 38. The slot in the sheath 726 in basically similar to that shown in the other embodiments.

The configuration of the pin 709 and the aperture 722 can have any desired shape so long as they are compatible so that the aperture can receive the pin.

Thus it can be seen that there is herein provided means for securely locking a used hypodermic needle assembly in a permanent, non-reversible position preparing it for safe disposal in an appropriate safe container.